

CERTIFICATE OF ANALYSIS

Product Name:	Pregabalin		
Batch No.	40031221224	Report Date	May 26, 2023
Manufacturing Date	December 26, 2022	Expiry Date TO	December 25, 2025
Package	20KG/ Drum	Batch size	51.61KG
Analytical results			
Items	Specifications		Results
Identification	(1) The IR spectrum of the test sample corresponds to the IR spectrum of the CRS		Complies
	(2) The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in Assay.		The retention time of the major peak of the sample solution: 10.528min The retention time of the major peak of the system solution: 10.530min
Enantiomer	NMT 0.15%		0.032%
Related Compound	Mandelic acid: NMT 0.10%		Not detected
	Isobutylglutaric acid ^a : NMT 0.15%		Not detected
	Isobutylglutar monoamide ^b : NMT 0.15%		Not detected
	Pregabalin related compound C: NMT 0.15%		NMT 0.0019%
	Maximum single impurity: NMT 0.10%		0.066%
	Total impurities: NMT 0.8%		0.10%
Loss on drying	NMT 0.5%		0.02%
Residue on ignition	NMT 0.1%		0.01%
Chloride	NMT 0.1%		Complies
Assay	Calculated on dried substance, it contains not less than 98.0% and not more than 102.0% of Acetazolamide (C ₈ H ₁₇ NO ₂)		100.50%
Conclusion	Complies with Specification of USP		

Inspector: Carlifor Wu

Verifier: Jack He

